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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/563,564

01/06/2006

Hisashi Sakamoto

10873.1791USWO

3665

52835

7590

03/05/2010

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EXAMINER

WHITE, DENNIS MICHAEL

ART UNIT

PAPER NUMBER

1797

MAIL DATE

DELIVERY MODE

03/05/2010

PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No. 10/563,564	Applicant(s) SAKAMOTO ET AL.	
	Examiner DENNIS M. WHITE	Art Unit 1797	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 23 November 2009.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1,6-8,14 and 15 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1,6-8,14 and 15 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 06 January 2006 is/are: a) ☐ accepted or b) ☒ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|-------------------------------------------------------------------------------------|-------------------------------------------------------------------|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

1. Amendments filed on 11/23/2009 are noted. Claims 2-5 and 9-13 are cancelled. Claims 1, 6-7 are amended. Claims 14-15 are new. Currently claims 1, 6-8 and 14-15 are pending.

Drawings

2. The drawings are objected to under 37 CFR 1.83(a). The drawings must show every feature of the invention specified in the claims. Therefore, a marker provided on the substrate must be shown or the feature(s) canceled from the claim(s). No new matter should be entered.

Corrected drawing sheets in compliance with 37 CFR 1.121(d) are required in reply to the Office action to avoid abandonment of the application. Any amended replacement drawing sheet should include all of the figures appearing on the immediate prior version of the sheet, even if only one figure is being amended. The figure or figure number of an amended drawing should not be labeled as "amended." If a drawing figure is to be canceled, the appropriate figure must be removed from the replacement sheet, and where necessary, the remaining figures must be renumbered and appropriate changes made to the brief description of the several views of the drawings for consistency. Additional replacement sheets may be necessary to show the renumbering of the remaining figures. Each drawing sheet submitted after the filing date of an application must be labeled in the top margin as either "Replacement Sheet" or "New Sheet" pursuant to 37 CFR 1.121(d). If the changes are not accepted by the examiner,

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the applicant will be notified and informed of any required corrective action in the next Office action. The objection to the drawings will not be held in abeyance.

Claim Rejections - 35 USC § 112

3. The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

4. Claim 15 is rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. The limitation regarding the sample analysis tool is fed in a direction orthogonal to a longitudinal direction of the sample analysis tool to be analyzed does not seem to be supported in the original disclosure.

5. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

6. Claim 15 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. It is unclear what “the direction orthogonal to a longitudinal direction of the sample analysis tool to be analyzed” is referring to. Is the sample analysis tool to be fed by being moved up, down,

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tangential, or sideways and thus keeping in the same position relative to the normal of the longitudinal direction? For examination purposes it will be interpreted that orthogonal refers to the tool to be fed a direction perpendicular relative to the longitudinal sample analysis tool.

Claim Rejections - 35 USC § 102

7. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

8. Claims 1, 6-8 and 14-15 are rejected under 35 U.S.C. 102(b) as being anticipated by Blumel et al (USP 4,279,514).

Regarding claims 1, 6-8, 14-15, Blumel et al teach an apparatus for the analysis of test tape comprising individual strips of test tape ("sample analysis tool") suitable for urinalysis. The test tape comprises several test areas 25, with each test area responding to different substances contained in the urine ("1 to 8 reagent pads"); and a white test area 101 ("1 to 3 balance pads"). The test areas 25 ("the reagent pad(s)") and the white test area 101 ("balance pad(s)") are provided on the substrate, the substrate and the reagent pad(s) are formed of different materials, the test areas 25 ("reagent pad(s)") are provided on a first end portion on a surface of the substrate, and arranged along a longitudinal direction of the substrate and concentrated at the first end portion of the substrate when 2 to 8 reagents pads are present (see Fig. 1, test areas concentrated on the side

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opposite of white test area 101 and black strip 99). It is noted that a friction coefficient of the portion on the surface where the reagent pad(s) are provided is higher than a friction coefficient of the surface of the substrate where the reagent pad(s) are not provided. The white test area 101 ("balance pad(s)") are provided on a second end portion of the substrate opposite to the first end portion at a distance from the test area 25 ("one of the balance pad(s) is provided at an end of the second end portion of the substrate so that friction balance of the surface of the sample analysis tool on which the reagent pad(s) are provided is adjusted and clogging when the sample analysis tool is supplied by a test piece feeder to an examination location is avoided").

Regarding claim 6-7, Blumel et al teach the test tape is suitable for urinalysis that are used as an aid in medical diagnosis. The tapes contain test areas which visibly discolor when they are brought into contact with certain substances contained in the urine ("reagent for a urinalysis" "physiologically active substances" "and one of the reagent pad(s) is provided for each selected test item") (col. 1 lines 16-28).

Regarding claim 8, Blumel et al teach the test tape ("sample analysis tool") is analyzed by a measuring device 17 ("an analyzer").

Regarding claim 14, Blumel teach the test tape further comprises a black strip 99 ("a marker provided on the substrate for discriminating front and rear surfaces of the substrate").

Regarding claim 15, Blumel et al teach the test tape with test areas 25 ("a strip-shaped substrate; and at least one reagent pad") on one side and a white

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test area 101 (“at least one balance pad”) on the other side (“wherein the at least one reagent pad is provided on a first end portion of the substrate, and the at least one balance pad is provided on a second end portion of the substrate opposite to the first end portion, so that friction balance of a surface of the sample analysis tool on which the at least one reagent pad is provided is adjusted”) (Fig. 1) are held in longitudinal receptacles of a rotating drum and scanned by a measuring device operative to sense light reflecting characteristics of test areas on each test tape (“sample analysis tool in combination with a sample analyzer by which the strip- shaped sample analysis tool is fed in a direction orthogonal to a longitudinal direction of the sample analysis tool to be analyzed”) (Fig. 2). The test tape is allowed to move on a feeding mechanism in the analyzer while maintaining the direction orthogonal to the longitudinal direction of the test tape.

Response to Arguments

9. Applicant's arguments with respect to claims 1, 6-8 and 14-15 have been considered but are moot in view of the new ground(s) of rejection.

Conclusion

10. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is

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filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to DENNIS M. WHITE whose telephone number is (571)270-3747. The examiner can normally be reached on Monday-Thursday, EST 8:00-5:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jill Warden can be reached on (571) 272-1267. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/LYLE A ALEXANDER/
Primary Examiner, Art Unit 1797
/dmw/